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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,856	04/10/2002	Olaf Weber	Le A 33 771	5595
7590	12/29/2004		EXAMINER	
Jeffrey M Greenman Bayer Corporation 400 Morgan Lane West Haven, CT 06516			FOLEY, SHANON A	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,856

Applicant(s)

WEBER ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 2 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

(Claim 2 is combined with claim 1 because amendments to the claim clearly indicate that the claim is directed to the non-enabling embodiment presented in claim 1.)

Applicant asserts that the working example clearly shows targeting properties of the recombinant paravirus because MDBK cells are penetrated faster with the recombinant compared to wild-type virus. Applicant also asserts that the results indicate that the heterologous protein is expressed on the surface, which leads to the increased penetration.

A full review of the working example and applicant's arguments have been fully considered, but are found unpersuasive. The results of the penetration assay on page 16 indicate that half of the gD-recombinant paramyxoviruses penetrated MDBK cells after 7 minutes, whereas the half of the wild-type viruses were able to penetrate MDBK cells after 20 minutes. Therefore, both types of viruses are obviously able to penetrate MDBK cells, regardless of whether the virus contains the gD gene. Faster penetration of the recombinant does not provide sufficient evidence that the virus has different, or altered, targeting properties compared with the

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wild-type virus. There is no indication from the working example that gD is expressed on the surface of the virus. There is also no evidence that the gD-virus is redirected, or targeted to a different ligand than the wild-type virus, since both viruses are able to penetrate the same cells. Applicant has not demonstrated that the concerns discussed by Boulanger et al., Vanderplasschen et al. and Dallo et al. are overcome by the instant invention. The teachings of Galmiche et al. are reiterated herein. Galmiche et al. show construction of EEV-type particles expressing a single chain antibody on the surface. Although the recombinant EEV particles of Galmiche et al. bind human adenocarcinoma cells in vitro, Galmiche et al. do not observe preferential infection toward these cells. This teaching indicates other yet-to-be identified factors affecting poxvirus infection. The instant disclosure does not teach how the skilled artisan could overcome the obstacles discussed in the art. In addition, the claims encompass using active and inactivated viruses. The working example uses active virus, but there is no guidance for making and using an inactive virus that possesses "targeting properties".

Applicant also argues that the therapeutic properties of parapox viruses are well known in the art. However, the therapeutic property of paraimmunity is not an issue.

Applicant states that the instant invention improves the therapeutic ability of the viruses so that generalized paraspecific is directly targeted to an effected location. However, applicant has not provided sufficient evidence to show that a recombinant ligand expressed on the surface of a parapoxvirus has been achieved, or that the recombinant parapoxvirus has altered tropism compared to a wild-type parapoxvirus.

Applicant cites the teachings of Robinson et al. demonstrating that manipulation of parapox viruses does not alter therapeutic properties. Unfortunately, this reference cannot be

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considered because a copy has not been provided. It is noted that the previous rejection also cites a "Robinson et al." reference on page 4 of the Office action. Although it cannot be determined whether the Robinson et al. cited by applicant is the same Robinson et al. cited in the rejection, it is clear from the teachings of the reference cited in the Office action that heterologous inserts do not alter paraimmunity of parapoxviruses, which is the point applicant appears to be making. However, the heterologous inserts of Robinson et al. (previously cited by the Office) are not expressed on the surface of the virus.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

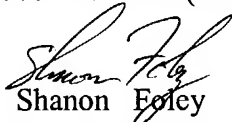
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
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